REMARKS

Favorable reconsideration of this application is respectfully requested in view of the following remarks.

Appreciation is expressed to Examiner Bouchelle for the indicated alllowability of Claims 13 and 14.

By way of this Amendment, independent Claims 1 and 15 have been amended in the manner discussed below in more detail. In addition, dependent Claims 3, 5, 7 and 9 have been amended in light of the changes to independent Claim 1. Claim 16 remains cancelled. Based on the indicated allowability of Claims 13 and 14, the only claims currently at issue in this application are Claims 1-12 and 15, with Claims 1 and 15 being the only independent claims.

As explained in the prior response, independent Claim 1 recites that the catheter at issue here comprises a sheath portion with a lumen extending therein, an insertion member slidably disposed in the lumen and provided with a distal end portion adapted to protrude from the distal end portion of the sheath portion, and an injection needle disposed at the distal end portion of the insertion member for injecting a therapeutic composition to a target tissue. Paired electrodes are disposed in the distal end portion of the catheter for measuring impedance, with at least one of the paired electrodes being disposed at the distal end portion of the insertion member.

The most recent Official Action notes that Chee et al. discloses a catheter in which paired electrodes 136, 138, 140 are disposed on a distal end probe. The Official Action recognizes that Chee et al. does not disclose positioning at least one of the paired electrodes 136, 138, 140 at the distal end portion of an insertion

member that is slidably disposed in the probe. The Official Action thus refers to the disclosure in Iancea et al. This latter patent discloses a stent delivery handle in which a catheter or other rail 194 is provided within a sheath 192. The patent states in lines 31-34 of column 8 that the distal end of the catheter or other rail 194 can be provided with a treatment element 196 such as an angioplasty balloon, a stent or other prosthesis and/or an array of electrodes. The Official Action comments that it would have been obvious in light of this disclosure in Iancea et al. to position the electrodes 136, 138, 140 disclosed in Chee et al. on an insertion member that is slidably disposed in the probe, instead of on the distal end probe 130, so that the electrodes can be positioned at the treatment location.

To more clearly define differences between the claimed catheter at issue here relative to the disclosures in the cited references, independent Claim 1 has been amended to recite that at least one of the paired electrodes is disposed at a bevel of the injection needle or at the distal end portion of the insertion member in the neighborhood of the bevel of the injection needle, with the at least one paired electrode being constructed to move into the target tissue when the target tissue is punctured by the injection needle.

In connection with the description of various disclosed embodiments of the catheter at issue here, the present application discloses, for example in paragraph [0143] together with the illustration in Fig. 16, that at least one of the paired electrodes can be disposed at a bevel of the injection needle. Also, the description in, for example, paragraph [0086] describes an electrode disposed in the neighborhood of the bevel of the injection needle. Further, the application describes in a number of places the way in which the position of the electrode(s) in the target

tissue can be advantageously utilized. For example, paragraph [0106] describes how the impedance values measured by the electrodes show a discernable difference when one of the electrodes is in the cardiac tissue and the remainder of the electrodes exist in the blood, when both electrodes are present in the blood, and when both electrodes are in the cardiac tissue.

As mentioned above, Iancea et al. describes providing a treatment element 196, which may be in the form of an array of electrodes, at the end of a catheter or rail 194. However, Iancea et al. does not disclose disposing one or more electrodes at a bevel of an injection needle or at a distal end portion of an insertion member in the neighborhood of the bevel of the injection portion. In addition, the array of electrodes mentioned in Iancea et al. is not constructed to be moved into target tissue when the target tissue is punctured by an injection needle. Indeed, Iancea et al. does not describe an injection needle and thus cannot be said to teach that one should position electrodes relative to the bevel of a needle in the claimed manner. Rather, as noted above, Iancea et al. merely discloses an array of electrodes forming a treatment element disposed at the end of a catheter or rail 194. It is thus respectfully submitted that the disclosure in Iancea et al. would not have motivated one of ordinary skill in the art to position the electrodes 136, 138, 140 disclosed in. Chee et al. at a bevel of an injection needle or at the distal end portion of an insertion member in the neighborhood of the bevel so that the at least one paired electrode is moved into the target tissue when the target tissue is punctured by the injection needle.

The method recited in independent Claim 15 has also been amended to recite that at least one of the paired electrodes is disposed at a bevel of the injection

needle or at the distal end portion of the insertion member in the neighborhood of the bevel of the injection needle, and to also recite moving the insertion member in a distal end direction relative to the sheath portion with the injection needle protruding from the distal end portion of the sheath portion to puncture the target tissue while moving one of the paired electrodes from the neighborhood of the target tissue into the target tissue. The therapeutic composition is injected through the injection needle into the target tissue after a change is detected in the impedance values as measured by the paired electrodes.

As pointed out above, Iancea et al. does not disclose disposing an electrode at the bevel of an injection needle or at the distal end portion of an insertion member in the neighborhood of the bevel. Iancea et al. also lacks disclosure of moving an electrode from a position in the neighborhood of the target tissue into the target tissue together with injecting a therapeutic composition through the needle into the target tissue after a change in the impedance value is measured by paired electrodes. Rather, Iancea et al. merely describes disposing a treatment element, which can be in the form of an array of electrodes, at the distal end of a catheter, with such catheter being positioned at a treatment location within a blood vessel.

It is thus respectfully submitted that the disclosure in Iancea et al. would not have motivated one to modify the method described in Chee et al. in a manner leading to the method recited in Claim 15.

As an additional point, the comments in the most recent Official Action indicate that it would have been obvious to place Chee et al.'s electrodes 136, 138, 140 on the insertion member that is movably positioned within the catheter instead of on the distal end probe "so that the electrodes can be positioned at the treatment

location." However, what is not explained in the Official Action is *why* one would want to position the electrodes 136, 138, 140 of Chee et al. at the treatment location. As pointed out in the prior response, the electrodes 136, 138, 140 disclosed in Chee et al. are not treatment electrodes that perform some form of treatment. Rather, as discussed in, for example, paragraphs [0095] and [0119], the electrodes 136, 138, 140 are specifically intended to sense contact between the distal end probe and the tissue surface. The patent notes in paragraph [0099] and illustrates in Fig. 5B that when the distal end probe contacts the tissue surface at an angle of 90° the electrodes conduct relatively little current, whereas when there is a lesser degree of contact between the distal end probe and tissue the electrodes conduct more current. Thus, the amount of current conducted gives an indication of the degree of contact of the distal end probe with the tissue surface.

It is true that Iancea et al. describes providing an array of electrodes as a treatment element on the distal end of a catheter. However, the disclosure in Iancea et al. of positioning such a treatment element at the distal end of a catheter has little relevance to the electrodes 136, 138, 140 disclosed in Chee et al. The reason quite simply is that the electrodes 136, 138, 140 in Chee et al. are not treatment electrodes. Rather, the electrodes 136, 138, 140 sense contact of the distal end probe and the tissue surface. It is thus respectfully submitted that a *prima facie* case of obviousness has not been established because it has not been shown why Iancea et al.'s disclosure of positioning *treatment electrodes* at the end of a catheter that is movably positioned within a sheath would have motivated one of ordinary skill in the art to similarly position the tissue surface sensing electrodes 136, 138, 140 disclosed in Chee et al. which are specifically provided for an entirely different purpose --

sensing contact with the tissue surface. Further, if one of ordinary skill in the art carried out the modification proposed in the Official Action, the electrodes 136, 138, 140 disclosed in Chee et al. would no longer perform their intended function of sensing contact between the distal end of the probe and the tissue surface. That is, upon positioning the electrodes 136, 138, 140 on an insertion member movably positioned within the distal end probe, it would no longer be possible to determine when the distal end probe is in contact with the tissue surface. This would be contrary to the reason why Chee et al. employs the electrodes 136, 138, 140.

The comment at the top of page six of the Official Action points out that Iancea et al. teaches "that the placement of the electrodes allows the clinician to advance the catheter to the treatment site." It appears there may be a misunderstanding concerning the discussion in lines 54-58 of column 8 of Iancea et al. This portion of the Iancea et al. disclosure merely describes that the treatment element (e.g., an array of electrodes) at the distal end of the catheter can be positioned at the treatment location (for example, a stent can be positioned across a stenotic region) using radiopaque markers associated with the distal end of the catheter-sheath assembly. Thus, Iancea et al. does not disclose that the electrodes allow a clinician to advance the catheter to the treatment site, but rather describes that the electrodes can be positioned at the treatment location by using radiopaque markers at the distal end of the catheter.

It is thus respectfully submitted that the disclosure in Iancea et al. would not have led one to modify the structure and method described in Chee et al. in a manner that would have resulted in the catheter and method recited in the claims at issue here.

The dependent claims define further distinguishing features and aspects of the claimed catheter and method. As these dependent claims depend from allowable independent claims, these additional distinguishing aspects and features are not discussed in detail at this time.

For at least the reasons set forth above, it is respectfully submitted all of the claims in this application are allowable. Accordingly, withdrawal of the rejections of record and allowance of this application are earnestly solicited.

Should any questions arise in connection with this application or should the Examiner believe that a telephone conference with the undersigned would be helpful in resolving any remaining issues pertaining to this application the undersigned respectfully requests that he be contacted at the number indicated below.

Respectfully submitted,

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